APPEAL BRIEF UNDER 37 C.F.R. § 41.37

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Richard E. Stein et al. Examiner: Lenwood Faulcon

Serial No.: 10/749,093 Group Art Unit: 3762

Filed: December 17, 2003 Docket: 279.B31US2

For: PATIENT CONTROLLED THERAPY MANAGEMENT AND DIAGNOSTIC DEVICE WITH HUMAN FACTORS INTERFACE

APPEAL BRIEF UNDER 37 CFR § 41.37

Mail Stop Appeal Brief- Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The Appeal Brief is presented in support of the Notice of Appeal to the Board of Patent Appeals and Interferences, filed on April 3, 2006, from the Final Rejection of claims 1-20 of the above-identified application, as set forth in the Final Office Action mailed on February 22, 2006.

This Appeal Brief is being filed within one-month (using the weekend rule) of the Decision on Appellant's Pre-Appeal Request for Review. Therefore, no extension of time is believed needed. However, if this understanding is deemed by the Patent Office to be in error, the Commissioner of Patents and Trademarks is hereby authorized to charge Deposit Account No. 19-0743 for any such extension of time.

The Commissioner of Patents and Trademarks is hereby authorized to charge Deposit Account No. 19-0743 in the amount of $500.00 which represents the requisite fee set forth in 37 C.F.R. § 41.2(b)(2). The Appellants respectfully request consideration and reversal of the Examiner's rejections of pending claims.

1. REAL PARTY IN INTEREST

The real party in interest of the above-captioned patent application is the assignee, CARDIAC PACEMAKERS, INC.

2. RELATED APPEALS AND INTERFERENCES

There are presently no other appeals or interferences known to Appellants that will have a bearing on the Board's decision in an appeal of this matter.

3. STATUS OF THE CLAIMS

Claims 1-20 are currently pending in this patent application. A Final Office Action was mailed on February 22, 2006. Claims 1-20 stand finally rejected and their rejection is the subject of the appeal of this matter.

4. STATUS OF AMENDMENTS

No amendments have been made subsequent to the Final Office Action dated February 22, 2006.

5. SUMMARY OF CLAIMED SUBJECT MATTER

Independent method claim 1 relates to displaying status information of a patient's heart rhythm. The status information is provided by a cardiac rhythm management device (*see, e.g.,* Application at FIG. 2 at 10) with deadfront status indicator lamps (*see, e.g.,* Application at FIG. 2 at 26, 28, 30, 32), where each lamp 26, 28, 30, 32 includes an icon that can be illuminated for viewing (*see* Application at page 5, lines 18-22). After querying an implantable device (*see, e.g.,* Application at FIG. 1 at 3) and receiving status information from the implantable device 3, the cardiac rhythm management device 10 displays the status using the status indicator lamps 26, 28, 30, 32.

Independent method claim 13 relates to displaying status information of a patient's heart rhythm by providing a cardiac rhythm management device (*see, e.g.,* Application at FIG. 2 at 10) with deadfront status indicator lamps (*see, e.g.,* Application at FIG. 2 at 26, 28, 30, 32). After querying an implantable device (*see, e.g.,* Application at FIG. 1 at 3) and receiving status information from the implantable device 3, the cardiac rhythm management device 10 displays the status using the status indicator lamps 26, 28, 30, 32.

Independent method claim 18 relates to displaying status information of a patient's heart rhythm by providing a cardiac rhythm management device (*see, e.g.,* Application at FIG. 2 at 10) with deadfront status indicator icons (*see, e.g.,* Application at FIG. 2 at 26, 28, 30, 32; *see* Application at page 5, lines 18-22) and a button (*see, e.g.,* Application at FIG. 2 at 24) on a case (*see, e.g.,* Application at FIG. 2 at 12). Activation of the button 24 initiates communication between the cardiac rhythm management device 10 and an implantable device (*see, e.g.,* Application at FIG. 1 at 3). During the communication, the cardiac rhythm management device 10 receives information and in response, illuminates at least one of the deadfront status indicator icons 26, 28, 30, 32 to visually communicate the information to the patient.

This summary does not provide an exhaustive or exclusive view of the present subject matter, and Appellants refer to the appended claims and its legal equivalents for a complete statement of the invention.

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1) Was a *prima facie* case of obviousness under 35 U.S.C. § 103(a) properly made with respect to claims 1-20 using Stanton et al. (U.S. Patent No. 6,249,703) in view of Nappholz et al. (U.S. Patent No. 5,720,770)?

7. ARGUMENT

A) The Applicable Law

The Examiner has the burden under 35 U.S.C. § 103 to establish a *prima facie* case of obviousness. *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d (BNA) 1596, 1598 (Fed. Cir. 1988). In combining prior art references to construct a *prima facie* case, the Examiner must show some objective teaching in the prior art or some knowledge generally available to one of ordinary skill in the art that would lead an individual to combine the relevant teaching of the references. *Id.* In agreement with the *In re Fine* court, the M.P.E.P. provides explicit direction to the Examiner:

> In order for the Examiner to establish a *prima facie* case of obviousness, three base criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *M.P.E.P.* § 2142 (citing *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d (BNA) 1438 (Fed. Cir. 1991)).

An invention can be obvious even though the suggestion to combine prior art teachings is not found in a specific reference. *In re Oetiker*, 977 F.2d 1443, 24 U.S.P.Q.2d (BNA) 1443 (Fed. Cir. 1992). However, while it is not necessary that the cited references or prior art specifically suggest making the combination, there must be some teaching somewhere which provides the suggestion or motivation to combine prior art teachings and applies that combination to solve the same or similar problem which the claimed invention addresses. One of ordinary skill in the art will be presumed to know of any such teaching. (See, e.g., *In re Nilssen*, 851 F.2d 1401, 1403, 7 U.S.P.Q.2d 1500, 1502 (Fed. Cir. 1988) and *In re Wood*, 599 F.2d 1032, 1037, 202 U.S.P.Q. 171, 174 (C.C.P.A. 1979)). However, the level of skill is not that of the person who is an innovator but rather that of the person who follows the conventional wisdom in the art. *Standard Oil Co. v. American Cyanamid Co.,* 774 F.2d 448, 474, 227 U.S.P.Q. 293, 298 (Fed. Cir. 1985). The requirement of a suggestion or motivation to combine references in a *prima facie* case of obviousness is emphasized in the Federal Circuit opinion, *In*

re Sang Su Lee, 277 F.3d 1338; 61 U.S.P.Q.2D 1430 (Fed. Cir. 2002), which notes that the motivation must be supported by evidence in the record.

The test for obviousness under § 103 must take into consideration the invention as a whole; that is, one must consider the particular problem solved by the combination of elements that define the invention. *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143, 227 U.S.P.Q. 543, 551 (Fed. Cir. 1985). References must be considered in their entirety, including parts that teach away from the claims. *See* MPEP § 2141.02. The fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 16 USPQ2d 1430 (Fed. Cir. 1990); M.P.E.P. § 2143.01.

B) The References

Stanton: describes an external patient programmer for facilitating control over an implanted medical device. The Stanton programmer provides tactile, audible, and visible feedback to the user to convey information regarding operation of the programmer and the implanted device (*see* Stanton at Abstract). The programmer can include a beeper and light-emitting diodes (LEDs) to indicate the status of the programmer or the implanted device (*see* Stanton at Abstract; FIG. 3).

Nappholz: describes an external device used to control the operation of a pacer (*see* Nappholz at Abstract). The external device has a speaker and a display to provide audible and textual alerts and information related to the operation of the pacer (*see* Nappholz at col. 9, lines 53-59).

C. Discussion of the Rejections

C.1 The Rejection of claims 1-20 using Stanton in view of Nappholz.

Appellants respectfully submit that there is no *prima facie* case of obviousness of claims 1-20 because (a) Stanton and/or Nappholz fail to disclose, teach, or suggest all elements of the present claims; and (b) there exists no motivation to combine these references in the manner used in the rejection.

C.1.a Neither Stanton nor Nappholz disclose, teach or suggest all elements

In particular, Appellants cannot find in the cited portions of these references any disclosure, teaching, or suggestion of "deadfront status indicator lamps each including a

deadfront icon that is illuminated for viewing on a front of the case" as recited in claim 1 and similarly recited in claims 13 and 18. Instead, Stanton apparently merely describes the use of LEDs to indicate whether a particular programming event has occurred (*see* Stanton at col. 14, lines 47-53). Stanton's several LEDs are apparently arranged with corresponding text on the body of the programmer to indicate various states or other status information regarding the implanted pulse generator (IPG) or the programmer (*see* Stanton at FIG. 3 at 32, 34, 36, 38). There is no indication that the LEDs in Stanton are used to illuminate any icon or other symbolic picture. Instead, Stanton's bare LEDs are simply exposed to the user to provide a binary state indication (e.g., on or off) (*see* Stanton at col. 6, lines 26-37).

In addition, Stanton fails to disclose, teach, or suggest "a deadfront icon that is illuminated for viewing on a front of the case" as recited in claim 1 and similarly recited in claim 13. The Final Office Action admits that Stanton only teaches positioning the LEDs on the bottom of the device (*see* Final Office Action at page 2; Stanton at FIG. 3). The Final Office Action asserts that Appellants have not shown any criticality of positioning the deadfront status indicators on the front of the case, thereby rendering such location obvious over Stanton. However, Appellants respectfully submit that the very nature of Appellants deadfront icon, which is capable of quickly communicating crucial clinical or other status information to a user, such as by using a graphical icon or symbolic picture, makes its frontal location critical. Therefore, Stanton's positioning of LEDs on the bottom of Stanton's device actually supports Appellant's position that information provided by Stanton's bare LEDs is completely different in kind from Appellant's crucial clinical or other status information.

Moreover, Nappholz fails to remedy the deficiencies of Stanton. In particular, Nappholz fails to disclose, teach, or suggest the use of LEDs to illuminate icons. The device described in Nappholz uses a display (*see* Nappholz at FIG. 5 at 66) to provide status and other information (*see* Nappholz at col. 6, lines 49-50; col. 9, lines 53-59). Nappholz's use of such a display obviates any need for Stanton's LEDs. Thus, neither Stanton nor Nappholz provide disclosure of the claimed elements, and there is no objective evidence of any motivation to combine Stanton and Nappholz, as further described below.

C.1.b There is no motivation to combine Stanton and Nappholz

Moreover, Appellants respectfully submit that the references provide absolutely no motivation to combine Stanton with Nappholz. The Final Office Action must provide specific, objective evidence of record for a finding of a suggestion or motivation to combine reference teachings and must explain the reasoning by which the evidence is deemed to support such a finding. *In re Sang Su Lee*, 277 F.3d 1338, 61 USPQ2d 1430 (Fed. Cir. 2002). However, the Final Office Action merely asserts:

> ... it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system as taught by Stanton et al. to include various warning/issue indicators to provide messages to a patient...

(Final Office Action at page 3). Appellants respectfully disagree with this vague and conclusory assertion, which is unsupported by any objective evidence. One of ordinary skill in the art certainly would not attempt to "improve" Stanton in this manner. As discussed above, Stanton apparently describes a system that includes "various warning/issue indicators to provide messages to a patient." However, in contrast to the illuminated icons that the present patent application describes, Stanton's device uses bare LEDs that provide a binary indication (on/off) or that blink in patterns to reflect implantable pulse generator (IPG) status (*see* Stanton at col. 14, line 47 to col. 15, line 6). Applicant cannot find anything in Stanton indicating any recognition of the limited usefulness of Stanton's bare LEDs.. As such, one of ordinary skill in the art would not necessarily look to improve Stanton's indicators as Stanton already provides indicators in one form—without any recognition of the shortcomings of such indicators.

Furthermore, even in the case of someone attempting to improve Stanton, one would not look to Nappholz to improve Stanton in this area. Stanton's device, which uses LEDs, is arguably sufficient for its very basic intended purpose; no objective evidence of record suggests that one should look to improve Stanton with a display as described in Nappholz. In addition, to the extent that an automobile may include an example of a deadfront status indicator, as indicated by the Final Office Action (*see* page 3), Appellants respectfully submit that this does not imply that one of ordinary skill in the medical device field would look to an automobile to "improve" the device disclosed in Stanton, particularly where there is no objective evidence of record of any recognition in the art of any serious limitation of the device of Stanton. Instead,

the rejection's asserted "motivation to combine" appears to be nothing more than the use of impermissible hindsight based on Appellants' own patent application to justify such a combination.

8. SUMMARY

In sum, because the cited combination of Stanton and Nappholz fail to set forth all elements recited or incorporated in the present claims and because no evidence of any motivation or suggestion to combine the references has been objectively established, Appellants respectfully submit that there is no *prima facie* case of obviousness of claims 1-20. Therefore, Appellants respectfully request reversal of all bases of rejection of all claims.

Respectfully submitted,

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 17 day of June, 2006.

Paula Suchy
Name

_____
Signature

CLAIMS APPENDIX

1. A method of displaying status information of a patient's heart rhythm comprising:

providing a cardiac rhythm management device having a plurality of deadfront status indicator lamps, a case sized to be held within the patient's hand, and a self-contained power supply within the case, the deadfront status indicator lamps each including a deadfront icon that is illuminated for viewing on a front of the case;

querying an implantable pulse generating device with the cardiac rhythm management device via wireless telemetry;

receiving status information from the implantable pulse generating device regarding the rhythm of the patient's heart; and

displaying the status information visually using the status indicator lamps.

2. The method of claim 1, further comprising generating an audible signal to communicate the status information in conjunction with the visual display.

3. The method of claim 2, wherein the audible signal is a voice signal.

4. The method of claim 3, wherein the voice signal includes natural language messages.

5. The method of claim 1, wherein the status information indicates that the patient's heart rhythm has been fast for more than forty-eight hours and a first deadfront status indicator lamp signaling fast rhythm and a second deadfront status indicator lamp signaling that the patient should contact a medical care provider are illuminated simultaneously.

6. The method of claim 5, wherein when the first and second deadfront status indicator lamps are illuminated to signal a persistent fast rhythm condition, no other visual or audible signals are generated by the cardiac rhythm management device.

7. The method of claim 1, wherein one of the plurality of deadfront status indicator lamps indicates when the cardiac rhythm management device has received information from the implanted pulse generating device that the current heart rhythm is within an acceptable range.

8. The method of claim 1, wherein one of the plurality of deadfront status indicator lamps indicates when the cardiac rhythm management device has received information from the implanted pulse generating device that the implantable device has detected that a condition of the implanted device or the heart rhythm is beyond acceptable parameters and the patient should contact a physician.

9. The method of claim 1, wherein one of the plurality of deadfront status indicator lamps indicates when the cardiac rhythm management device has received information from the implanted pulse generating device that a shock by the implanted pulse generating device has been scheduled.

10. The method of claim 1, wherein a fourth deadfront status indicator icon indicates when the telemetry circuitry has received information from the implantable device that the current heart rhythm is not within normal rhythm parameters.

11. The method of claim 1, wherein the cardiac rhythm management device further includes a therapy request button mounted in the case, and depressing the therapy request button causes the cardiac rhythm management device to initiate a shock therapy with the implanted device.

12. The method of claim 1, wherein the cardiac rhythm management device further includes a status inquiry button that is mounted in the case, and depressing the status inquiry button causes the cardiac rhythm management device to query the implanted device and receive information from the implanted device.

13. A method of displaying status information of a patient's heart rhythm using a cardiac rhythm management device, the cardiac rhythm management device including a case sized to be held within the patient's hand, a plurality of deadfront status indicator lamps exposed for viewing on a front of the case, a plurality of LEDs within the case, and a self-contained power supply within the case, the method comprising:

querying a pulse generating device with the cardiac rhythm management device via wireless telemetry, the pulse generating device being implanted within the patient;

receiving status information from the implanted pulse generating device with the cardiac rhythm management device, the information regarding the patient's heart rhythm; and

illuminating at least one of the deadfront status indicator lamps using at least one of the plurality of LEDs, thereby displaying the status information visually.

14. The method of claim 13, wherein the deadfront status indicator lamps each include an icon, and illuminating the icon with at least one of the plurality of LEDs makes the icon visible.

15. The method of claim 13, wherein each of the plurality of LEDs emits a different color and displaying the status information includes a combination of colors from the LEDs and images from the deadfront status indicator lamps.

16. The method of claim 13, wherein the cardiac rhythm management device includes first and second buttons, the first button configured to initiate querying of the implanted pulse generating device and receiving of the status information, and the second button configured to initiate a shock therapy with the implanted device in response to the displayed status information.

17. The method of claim 13, wherein the cardiac rhythm management device includes four deadfront status indicator lamps and four LEDs, and illuminating at least one of the deadfront status indicator lamps includes simultaneously illuminating two or more of the deadfront status indicator lamps.

18. A method of communicating information about a patient's heart using a cardiac management device, the cardiac management device including a case, a plurality of deadfront status indicator icons exposed for viewing on the case, a plurality of light generating members within the case, and at least one button mounted in the case, the method comprising:

activating the button to initiate communication via wireless telemetry between the cardiac management device and a pulse generating device that is implanted in the patient, wherein the wireless telemetry communication includes receiving information related to the patient's heart from the implanted pulse generating device with the cardiac management device; and

illuminating at least one of the deadfront status indicator icons using at least one of the plurality of light generating members to visually communicate the information to the patient.

19. The method of claim 18, wherein each deadfront status indicator is illuminated by a separate light generating member.

20. The method of claim 18, wherein the wireless telemetry communication includes receiving information related to a condition of the implanted device.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.